K041716

JUL 22 2004

510(k) Summary per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation (BSC) Two Scimed Place Maple Grove, MN 55311
Contact Name and Information	Name: Maureen Montbriand Title: Regulatory Affairs Specialist Telephone: 763-494-2903 Facsimile: 763-494-2981 e-mail: montbrim@bsci.com
Date Prepared	June 23, 2004
Proprietary Name(s)	PTFE Felts and Pledgets
Common Name	Intracardiac patch or pledget made of polytetrafluoroethylene
Product Code	DXZ
Classification of Device	Class II, 21 CFR Part 870.3470
Predicate Device	PTFE Felts and Pledgets (Preamendment devices)
Device Description	The PTFE Felts and Pledgets are manufactured from 100% polytetraflouroethylene fibers. The felt is purchased from an outside supplier in bulk, which is then heat set, scoured and cut into squares, offering two sizes, or punched into oval, round, square or rectangular pledgets. The Felts have a nominal thickness of 1.245mm (0.049"). The Pledgets have a nominal thickness of either 0.99mm (0.039") or 1.245mm (0.049") depending upon size.
Intended Use of Device	**Felts:** Indicated for Ventricular aneurysmectomy; tissue prosthesis, and suture buttressing. **Pledgets**: Indicated for Tissue, prosthesis, and suture buttressing.
Summary of Substantial Equivalance	The PTFE Felts and Pledgets have been tested. All data gathered has demonstrated that the device is Substantially Equivalent to the predicate device. No new issues of safety and efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Boston Scientific Corporation
c/o Ms. Maureen Montbriand
Regulatory Affairs Specialist
Two Scimed Place B220
Maple Grove, MN 55311-1566

Re: K041716
PTFE Felts and Pledgets
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: Class II
Product Code: DXZ
Dated: June 23, 2004
Received: June 24, 2004

Dear Ms. Montbriand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna R. Vo Ahmed

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041716

Indications for Use

510(k) Number (if known)	Preamendment device
Device Name	PTFE Felts and Pledgets
Indications For Use	**Felts:** Indicated for Ventricular aneurysmectomy; tissue prosthesis, and suture buttressing. **Pledgets**: Indicated for Tissue, prosthesis, and suture buttressing.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mechanic

(Division Sign-Off)
Division of Cardiovascular Devices

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